UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PHYLLIS LEVITT, on behalf of herself and all others similarly situated, Plaintiff, v. LEO PHARMA INC. and LEO PHARMA A/S, Defendants.	Civil Action No. **CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff Phyllis Levitt ("Plaintiff") brings this action on behalf of herself and all others similarly situated against Defendants LEO Pharma Inc. and LEO Pharma A/S (collectively "LEO Pharma" or "Defendants"). Plaintiff makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to the allegations specifically pertaining to herself, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a class action lawsuit about LEO Pharma's manufacturing and distribution of prescription Picato gel (ingenol mebutate) ("Picato"). Picato was indicated to treat precancerous actinic keratosis, but it instead increased the risk of squamous cell skin cancer. Accordingly, Picato is worthless and Defendants should be required to fully refund consumers like Plaintiff.

2. LEO Pharma has sold Picato in the United States since 2012.

3. Picato is used to treat actinic keratosis, a scaly, crusty lesion on the skin, caused by too much sunlight exposure.

4. For the treatment of actinic keratosis on the face or scalp, LEO Pharma

recommended applying a 0.015% formulation of Picato gel to the affected area once daily for three consecutive days. For the treatment of actinic keratosis on the trunk or extremities, LEO Pharma recommended applying a 0.05% formulation of Picato gel to the affected area once daily for two consecutive days.

5. In September 2019, following reports of Picato-related skin cancer incidents, the European Commission requested a safety review of the drug.

6. In January 2020, the European Medinces Agency ("EMA") suspended sale of Picato while its Pharmacovigilance Risk Assessment Committee ("PRAC") conducted the review.

7. The January 2020 EMA suspension announcement cited troubling results from several studies and clinical trials:

- The final results of a three-year study in 484 patients showed a higher incidence of skin malignancy with ingenol mebutate than with the comparator imiquimod (3.3% of patients developed cancer in the Picato group versus 0.4% in the comparator group).
- A higher incidence of skin tumours occurred in the ingenol mebutate arm of an 8-week vehicle-controlled trial in 1,262 patients (1% of patients in the ingenol mebutate arm versus 0.1% in the vehicle arm).
- In addition, in four clinical trials involving 1,234 patients with a related ester, ingenol disoxate, a higher incidence of skin tumours occurred with ingenol disoxate than with a vehicle control (7.7% versus 2.9% of patients, respectively). As ingenol disoxate is closely related to Picato, the results were considered relevant in the ongoing review of Picato.

8. In February 2020, LEO Pharma requested that its marketing authorization in the EU be withdrawn.

9. In April 2020, PRAC issued a report confirming that Picato "may increase the risk of skin cancer" and concluded "that the risks of the medicine outweigh its benefits." PRAC added that "Picato's effectiveness is not maintained over time and noted that other treatment options are available for actinic keratosis."

10. The PRAC report included the following information for healthcare professionals:

- Studies have found a higher incidence of skin tumours, especially squamous cell carcinoma, in the treatment area in patients treated with Picato (ingenol mebutate) or ingenol disoxate (a related ester not currently authorised and no longer in development) than with a comparator or vehicle (gel not containing any active substance).

- In the final results of a 3-year safety study in 484 patients, skin tumours were observed inside the treatment area in 6.3% of patients treated with ingenol mebutate compared with 2% of those treated with imiquimod. The difference was driven by squamous cell carcinoma (3.3% versus 0.4% of patients) and Bowen's disease (2.5% versus 1.2%).

- In a pooled analysis of four 14-month trials involving 1234 patients, higher incidence of tumours, including basal cell carcinoma, Bowen's disease and squamous cell carcinoma, was seen with the related ester ingenol disoxate than with vehicle (7.7% versus 2.9% of patients).

- Picato has already been taken off the market and is therefore no longer a treatment option for actinic keratosis.

- Other treatment options for actinic keratosis include topical diclofenac, fluorouracil and imiquimod, as well as photodynamic therapy, cryotherapy, curettage or excisional surgery.

- Healthcare professionals should advise patients who have been treated with Picato to be vigilant for any skin lesions developing and to seek medical advice promptly should any occur. Time to onset can range from weeks to months following treatment.

11. The EMA warned patients treated with Picato that they "should look out for unusual skin changes or growths, which could occur from weeks to months after use, and seek medical advice if any occur."

12. In July 2020, Health Canada, the department of the Government of Canada responsible for national health policy, issued a report stating that it had reviewed 29 case reports of skin cancer in patients treated with Picato, and that "26 cases were found to be possibly linked."

13. In addition, Health Canada "assessed 12 studies published in scientific and

medical literature in order to determine the link between the use of Picato and skin cancer" and "found that 6 of the 12 studies had evidence of skin cancer with the use of Picato."

14. Based on this evidence, Health Canada concluded "that there may be a link between Picato and the risk of skin cancer."

15. In October 2020, at Health Canada's request, LEO Pharma Inc. initiated a recall of Picato from the Canadian market.

16. Health Canada advised patients being treated with Picato to "stop their treatment" and to "contact their healthcare professional to discuss other treatment options."

17. Health Canada also advised patients to "monitor and immediately report to their healthcare professional any signs or symptoms of skin cancer, such as new scaly red patches on their skin, open sores, or elevated or warty growths within the treatment area, which could occur after stopping treatment."

18. In October 2020, LEO Pharma announced that it would permanently discontinue the manufacture of Picato.

PARTIES

19. Plaintiff Phyllis Levitt is a citizen of New York who resides in Mt. Kisco, New York. In or about January 2015, Ms. Levitt's doctor diagnosed her with actinic keratosis and prescribed Picato. Immediately thereafter, Ms. Levitt filled her prescription for Picato at the Northern Westchester Prescription Center ("NWPC") located in Mr. Kisco, New York and used the Picato as directed by her doctor. Ms. Levitt filled another prescription for Picato at the same pharmacy in or about June 2015. Ms. Levitt purchased the Picato using her insurance, and she paid a total of approximately $364.42 out of pocket in copayments. The Picato that Ms. Levitt purchased was manufactured by LEO Pharma A/S, distributed by LEO Pharma Inc. and sold by

NWPC. When purchasing the Picato, Ms. Levitt reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were properly designed, effective, free from defects and safe. Ms. Levitt relied on these representations and warranties in deciding to purchase Picato from Defendants, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased Picato if she had known that it was not, in fact, properly designed, effective, free from defects and safe.

20. Defendant LEO Pharma Inc. is a corporation incorporated under the laws of Delaware with a principal place of business at 7 Giralda Farms, 2nd Floor, Madison, New Jersey 08807. LEO Pharma Inc. is a wholly owned subsidiary of Defendant LEO Pharma A/S. LEO Pharma Inc. conducts substantial business in the United States, and specifically in the State of New York. LEO Pharma Inc. distributes and sells Picato in the United States, including in the State of New York.

21. Defendant LEO Pharma A/S is a corporation incorporated under the laws of Denmark with a principal place of business at Industriparken 55, DK-2750, Ballerup, Denmark. LEO Pharma A/S conducts substantial business in the United States, and specifically in the State of New York. LEO Pharma A/S manufactures Picato, which it sells in the United States, including in the State of New York, through its agent and wholly-owned subsidiary LEO Pharma Inc.

JURISDICTION AND VENUE

22. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendants, there are more than 100

members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

23. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because many of the acts and transactions giving rise to this action occurred in this District, and because Defendants (a) are authorized to conduct business in this District and have intentionally availed themselves of the laws and markets within this District through the promotion, marketing, distribution, and sale of Picato in this District; (b) conduct substantial business in this District; and (c) are subject to personal jurisdiction in this District.

CLASS ALLEGATIONS

24. Plaintiff seeks to represent a class defined as all persons in the United States who purchased Picato (the "Class"). Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendants, Defendants' officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendants and/or Defendants' officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

25. Plaintiff also seeks to represent a subclass of all Class members who purchased Picato in New York (the "New York Subclass").

26. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class and New York Subclass may be expanded or narrowed by amendment or amended complaint.

27. **Numerosity.** The members of the Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon

information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of members in the Class. Although the precise number of Class members is unknown to Plaintiff, the true number of Class members is known by Defendants and may be determined through discovery. Class members may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendants and third-party retailers and vendors.

28. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the Picato manufactured, distributed, and sold by Defendants poses an unreasonably high risk of causing cancer in users;

(b) Whether Defendants' conduct was in violation of New York's General Business Law;

(c) whether Defendants are liable to Plaintiff and the Class and New York Subclass for unjust enrichment;

(d) whether Defendants are liable to Plaintiff and the New York Subclass for violations of the New York consumer protection law;

(e) whether Plaintiff and the Class and New York Subclass have sustained monetary loss and the proper measure of that loss; and

(f) whether Plaintiff and the Class and New York Subclass are entitled to restitution and disgorgement from Defendants.

29. **Typicality.** Plaintiff's claims are typical of the claims of the other members of the Class and New York Subclass in that Defendants mass marketed and sold defective Picato to

consumers throughout the United States. This defect was present in all of the Picato manufactured, distributed, and sold by Defendants. Therefore, Plaintiff's claims are typical in that they were uniformly harmed in purchasing and using the defective Picato. Plaintiff's claims are further typical in that Defendants deceived Plaintiff in the very same manner as they deceived each member of the Class and New York Subclass. Further, there are no defenses available to Defendants that are unique to Plaintiff.

30. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Class and New York Subclass. Plaintiff has retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on behalf of the Class and New York Subclass. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class and New York Subclass.

31. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class and New York Subclass members are relatively small compared to the burden and expense of individual litigation of their claims against Defendants. It would thus be virtually impossible for the Class and New York Subclass, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class and New York Subclass members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual

management difficulties under the circumstances.

32. In the alternative, the Class and New York Subclass may also be certified because:

(a) the prosecution of separate actions by individual Class and New York Subclass members would create a risk of inconsistent or varying adjudications with respect to individual Class and New York Subclass members that would establish incompatible standards of conduct for the Defendants;

(b) the prosecution of separate actions by individual Class and New York Subclass members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class and New York Subclass members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendants have acted or refused to act on grounds generally applicable to the Class and New York Subclass as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class and New York Subclass as a whole.

COUNT I
Unjust Enrichment
(On Behalf Of The Class And New York Subclass)

33. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

34. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

35. Plaintiff and the Class and New York Subclass conferred a benefit on Defendants in the form of monies paid to purchase Defendants' defective Picato.

36. Defendants voluntarily accepted and retained this benefit.

37. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for medications unfit for human use, it would be unjust and inequitable for the Defendants to retain it without paying the value thereof.

COUNT II
Violation Of New York General Business Law § 349
(On Behalf Of The New York Subclass)

38. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

39. Plaintiff brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendants.

40. New York's General Business Law § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

41. In its sale of goods throughout the State of New York, Defendants conduct business and trade within the meaning and intendment of New York's General Business Law § 349.

42. Plaintiff and members of the New York Subclass are consumers who purchased products from Defendants for their personal use.

43. By the acts and conduct alleged herein, Defendants have engaged in deceptive, unfair, and misleading acts and practices, directed at consumers, which include, without limitation, selling Picato without informing consumers that is carcinogenic, unfit for human use and ineffective for treating actinic keratosis.

44. The foregoing deceptive acts and practices were directed at consumers.

45. The foregoing deceptive acts and practices were misleading in a material way

because they constituted material omissions that fundamentally misrepresented the characteristics and quality of Picato to induce consumers to purchase the same.

46. By reason of this conduct, Defendants engaged in deceptive conduct in violation of New York's General Business Law.

47. Defendants' actions are the direct, foreseeable, and proximate cause of the damages that Plaintiff and members of the New York Subclass have sustained from having paid for and used Defendants' products.

48. As a result of Defendants' violations, Plaintiff and members of the New York Subclass have suffered damages because: (a) they would not have purchased Picato on the same terms if they knew that Picato was carcinogenic, unfit for human use and ineffective for treating actinic keratosis, and (b) Plaintiffs paid a premium in the amount of the full purchase price of the medication as a result of Defendants' deceptive acts and practices.

49. On behalf of herself and other members of the New York Subclass, Plaintiff seeks to recover her actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT III
Violation Of New York General Business Law § 350
(On Behalf Of The New York Subclass)

50. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

51. Plaintiff brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendants.

52. New York's General Business Law § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

53. Pursuant to said statute, false advertising is defined as "advertising, including labeling, of a commodity … if such advertising is misleading in a material respect."

54. GBL § 350 claims may be based on omissions, in addition to affirmative misrepresentations. *In re Evergreen Mut. Funds Fee Litig.*, 423 F. Supp. 2d 249, 264 (S.D.N.Y. 2006); *Newman v. RCN Telecom Servs., Inc.*, 238 F.R.D. 57, 77 (S.D.N.Y. 2006) (explaining that both misrepresentations and omissions are actionable under GBL §§ 349 and 350).

55. Based on the foregoing, Defendants have engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising by omission in violation of Section 350 of New York's General Business Law.

56. Defendants' misleading and deceptive omissions of material fact were directed towards consumers.

57. Defendants' misleading and deceptive omissions of material fact were likely to mislead a reasonable consumer acting reasonably under the circumstances.

58. Defendants' misleading and deceptive omissions of material fact resulted in consumer injury or harm to the public interest.

59. As a result of Defendants' misleading and deceptive omissions of material fact, Plaintiff and the New York Subclass have suffered and continue to suffer economic injury.

60. As a result of Defendants' violations, Plaintiff and members of the New York Subclass have suffered damages due to said violations because: (a) they would not have purchased Picato on the same terms if they knew that it was carcinogenic, unfit for human use and ineffective for treating actinic keratosis, and (b) Plaintiffs paid a premium in the amount of the full purchase price of the medication as a result of Defendants' deceptive acts and practices.

61. On behalf of herself and other members of the New York Subclass, Plaintiff seeks

to recover her actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendants, as follows:

A. For an order certifying the nationwide Class and the New York Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiff as representative of the Class and New York Subclass and Plaintiff's attorneys as Class Counsel to represent the Class and members of the New York Subclass;

B. For an order declaring the Defendants' conduct violates the statutes referenced herein;

C. For an order finding in favor of Plaintiff, the nationwide Class, and the New York Subclass on all counts asserted herein;

D. For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;

E. For prejudgment interest on all amounts awarded;

F. For an order of restitution and all other forms of equitable monetary relief;

G. For injunctive relief as pleaded or as the Court may deem proper; and

H. For an order awarding Plaintiff and the Class and New York Subclass their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all issues in this action so triable of right.

Dated: March 16, 2021

Respectfully submitted,

BURSOR & FISHER, P.A.

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